

Evidence on Article 5.3 of FCTC (Tobacco Industry Interference in tobacco control activities) in India- a Qualitative scoping study

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Abstract

Background: Tobacco Industry (TI) strives to portray itself as being “socially responsible” and contest for pertinent decision-making positions, which it uses to deter, delay or dilute tobacco control measures. There is little documented evidence of Tobacco Industry Interference (TII) from India, the scope of their interference and challenges faced by the experts for effective tobacco control.

Methods: A cross-sectional qualitative research design, based upon in-depth interviews (N=26), was used to explore the opinion of key stakeholders regarding TII in India. The interview schedule collected information about the participant’s roles and responsibilities in tobacco control, the nature of TII faced by the participant, means of influence by TI, barriers and challenges to tobacco control efforts using a set of questions.

Results: Most of the respondents were engaged in tobacco control, training, advocacy, and awareness generation activities from the last 5-10 years or more. The respondents defined the TI and its scope as per their experience with the help of power ranking methodology. Most of them perceived TI as ‘Manufacturers’ while others consider them as ‘advertisers’, ‘public relation companies’, ‘wholesalers’, ‘vendors’, and ‘Government firms having TI stocks’ as TI. We identified six major domains (Influencing the policy and administrative decisions, Interference with implementation of tobacco control laws and activities, False propaganda and hiding the truth, manipulating front action groups (FAG), Rampant tobacco advertising and promotion activities, and others) under which TII activities were classified. Most respondents were of opinion that TI players were interfering in the policy decisions, implementation of the tobacco control laws and activities, and manipulating the FAG. A detailed taxonomic classification of the TII strategies that emerged from our analysis were linked to article 5.3 of FCTC.

Conclusions: The activity documented a significant level of TII in different domains with stakeholders acting at various hierarchical levels. The study provide insights about the nefarious tactics of TI, enable stakeholders to anticipate and pre-empt the kinds of alliances the TI may attempt to build, stimulate academicians and researchers to undertake in-depth analysis into various strategies and underscore the need for ensuring transparency in official interactions with the TI and their representatives.

Background

About 275 million tobacco users resides in India[1]. It is also illustrated for widespread production and consumption of various forms of tobacco. Due to such high usage of tobacco, Indian have one of the highest rates of oral cancer in the world, with an annual incidence as high as 10 per 100,000 among males[2]. This high burden makes it one of the most important preventable public health problems. Therefore, the Tobacco Industry (TI) needs to be treated differently from other industries, due to the fundamental conflict between their goals. Global evidence suggests that the TI is a formidable opponent of public health and development, which is determined to recruit new tobacco users at the cost of public health. TI constantly portrays and reinvents itself as being “socially responsible” and therefore eligible for a seat at policymaking positions, which it uses to deter, delay or dilute tobacco control measures[3]. It has now been firmly recognised by public health organisations that TI and its associated front groups along with their diverse partners are the leading cause of the persistent tobacco use [4]. Despite the adoption of the Cigarettes and Other Tobacco Products Act (COTPA) in 2003, and subsequent launch of the National Tobacco Control Program in 2007, TI has actively opposed and undermined the Government’s efforts to present evidence and countered evidence-backed policies to protect people from harms of tobacco use[5,6]. Thus, a strong political commitment at global and regional level is needed to counter the hydra-headed TI to protect health of citizens.

Eliminating TII in health policies is potentially the single most effective measure that governments can adopt to protect tobacco control activities, thereby addressing the death and disease caused by tobacco epidemic. Article 5.3 of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) and its guidelines provide a roadmap for why and how tobacco industry interference (TII) in health policies must be eliminated[7]. The Article calls for measures by the governments to defend health policy “from commercial and other vested interests of the TI”[8]. Also, the parties to the FCTC are obligated to objectively submit reports pertaining to the efforts made for strict implementation of the provisions, including the article 5.4 on a regular basis to the Convention Secretariat[9]. In 2008, the Conference of the Parties (COP) to the FCTC adopted a series of guidelines and recommendations for the implementation of Article 5.3[10]. WHO Article 5.3 has a set of guideline recommendations pertaining to awareness raising (recommendations 1.1–1.2), on limiting interactions with the tobacco industry (recommendations 2.1–2.2), on the rejection of industry partnerships (recommendations 3.1–3.4), on the avoidance of conflicts of interest (recommendations 4.1–4.11), on transparency (recommendations 5.1–5.5), on the denormalization of industry “corporate social responsibility” activities (recommendations 6.1–6.4), on preferential treatment of the tobacco industry (recommendations 7.1–7.3), and on state-owned tobacco industries (recommendations 8.1–8.3).

Despite this global agreement, TI has been extending its scope to control policy and legislation of various countries using broad array of techniques which included testimonies, position papers, constituency letters, contacts and face-to-face discussion between representatives from TI and legislators for attainment of its objective to obstruct, annul, amend or halt pending legislation [11]. A detailed report of the Corporate Accountability International comprehensively captures the interference, which comprises destabilizing and making use of legislative ambiguities, demanding a seat at government negotiating tables, advocating voluntary regulation instead of legislation, drafting and distributing sample legislation which is advantageous to the TI, questioning and stretching government timetables for implementing laws, trying to influence legislators, gaining favour by funding government schemes on other health issues and preserving trade benefits at the cost of health [11,12].

Besides weakening legislation in almost all developing countries that have a significant number of smokers[13–15] and launching specific scathing attacks on governments to prevent its extermination [16], TI uses tactics to undermine the importance of various scientific studies done to generate evidence regarding deleterious impacts of tobacco[17]. This fact was highlighted by TI documents which clearly state that TI feared such studies which would lead to greater restrictions on smoking and therefore initiated attempts to nullify them through counter research, altering media and public opinion, and lobbying administration[17]. Given the power and size of the TI, such initiatives can have a significant impact on legislative initiatives in different countries[18]. Also, it is now clear that TII is not circumscribed by the geographic boundaries and TI has adopted strategies to alter policy decisions at local levels that brings a much bigger effects[19]. Reports from developed countries have explicitly delineated the heinous and nefarious acts of TII[11,20]. However, there is little evidence from India that has attempted to analyse the TII, their direct and indirect allies, and their modus-operandi. With this context, the main objective of the study was to document the evidence on Article 5.3 of WHO FCTC implementation and related violations in India over the last decade (2007-2017). Specifically, we explored different stakeholders involved in TI, the nature of interactions between the TI and diverse actors (front groups) who influence tobacco control at the behest of the TI in India. This is amongst the very first attempts from India (and amongst few attempts globally) to document the evidence of TII in tobacco control activities through evidence-based discussions, and suggestions of the experts intended to present as a ready-made material for the policy-makers.

Methods

Study design: This was a scoping study, based upon in-depth interviews, as we intended to document the range, extent and nature of TII in India [21]. In the study, when data on the ‘perception of TI’ and ‘means of TII in India’ were obtained, they were prioritized using power ranking method [22].

Study Settings and Participants: Initially, a series of meetings among the investigators of two government institutes of national excellence of India (referred as Institute 1 and Institute 2 respectively thereafter) along with the representatives from funding partners viz. International Union against TB and Lung Diseases (The Union), South East Asia, New Delhi; and WHO Country office for India were conducted to frame the study protocol, in-depth interview schedule and the list of key informants for in-depth interviews through detailed deliberations.

Inclusion criteria: Irrespective of the years of experience, the stakeholders of tobacco control in India who have served between the years 2007 and 2017 as a member of a civil society / researcher / program manager / policymaker: in various capacities (at state and national levels) and agencies (government, private and non-governmental) were enlisted as key informants for the study. For the power ranking method, participants were chosen depending on their expertise in tobacco control as substantiated by the richness of information on tobacco industry interferences, shared during the in-depth interviews.

Sample and Sampling method: We approached 30 stakeholders, irrespective of number of years of experience in tobacco control. Purposive sampling technique was employed to select the participants who could provide in-depth information on the study topic. Four respondents denied consent for the interview and we could finally interview 26 stakeholders. For employing power ranking method, a panel of ten key informants who participated in the in-depth interviews were selected using purposive sampling.

Study tool: The in-depth semi-structured interview schedule (*Supplementary File 1*) was developed and used to collect the desired information. The interview schedule collected information on the socio-demographic characteristics participant's roles and responsibilities in tobacco control, the nature of TII faced by the participant, means of influence by TI, barriers and challenges to tobacco control efforts using a set of ten questions. The interview schedule was pre-tested, and required modifications were made after discussion.

Based on the findings of in-depth interviews, ranking sheets were developed for prioritizing the 'perceptions of tobacco industry' and 'means of TII in India', evolved from the interviews. (*Supplementary File 2 & 3*)

Data collection: The participants were contacted over e-mails for determining their willingness after explaining the study purpose and procedures through the consent form and Participant Information Sheet. The confidentiality and anonymity of the participants were assured. After receiving their consent, a convenient time and method for data collection (Telephone or by Face-to-Face) was determined. In case of non-responders, two reminders (through email) within a gap of two weeks were sent followed by prompting through telephonic reminders to boost response rates. Alongside, two researchers who had a prior experience in conducting qualitative research interviews were recruited and trained in collecting data by the team of study investigators.

Each participant interview was audio-recorded and it was transcribed in English. During the interviews, field notes were taken to capture contextual details and non-verbal information. Field notes were shared with the participants at the end of interviews to ascertain accuracy. Each interview lasted for an approximate 40-45 minutes.

Power ranking method was carried out through a consultative meeting, with the findings of in-depth interviews, among the investigators and selected key informants. The second investigator served as moderator for the meeting. Participants were first described about the process of rank ordering of responses collated from the in-depth interviews, using respective questionnaires.

Rank ordering was done in two steps. In the first step, the participants were asked to rank order their 'perception of TI' and 'means of TII in India' based on their individual priorities. In both the lists, the participants ranked the responses between 1 and 17 such that "1" represented least representative and "17" corresponded to most representative of

tobacco industry/means to TII. The individual rank orders were aggregated to develop the consolidated lists on 'perception of TI' and 'means of TII in India'.

In the step two, the collated lists were displayed to the participants with an object to construct the final prioritized order of responses of both lists through iterative process. Here, the facilitator encouraged each participant to critically evaluate the aggregated lists and sought reordering of prioritized responses if needed. When a participant suggested reordering a response in the lists, the facilitator sought consensus from others with the positioning, as well as invited them to reposition it as appropriate. Adjusting the positions of responses in the lists continued until final order of responses was arrived among the group members.

Analysis: Verbatim transcripts were analyzed systematically using inductive approach of qualitative content analysis. For analysis, each interview transcript was read several times to identify textual segments relevant to the research questions under study. Relevant texts when identified were initially assigned codes along with descriptive labels. Subsequently, whenever related texts were found, were allotted to previously coined codes and newer codes, for emerging textual segments. Data collection and analysis were conducted concurrently to facilitate generation of codes according to data stemming from participants interviews.

A framework of codes developed in the process was then grouped into sub-categories, sub-themes and major themes, based on similarities and differences between the codes. Once the sub-themes and themes were generated, they were compared with the textual segments of the interview transcripts to ensure that the themes reflected the message conveyed by the participants during the interviews.

Two of the investigators were involved in data triangulation. After themes and sub-themes were generated for each transcript individually, the interview data along with the field notes was exchanged electronically for validation of interpretations (codes, sub-themes and themes) made. When discrepancies arose during the validation process, the interpretation by the Principal Investigator was considered the final.

The results are presented in a descriptive manner under major themes derived from the study. They are substantiated with relevant quotations from the interview transcripts. Repeated and unnecessary words were removed from the quotes to enhance understandability while retaining its essence.

In Power ranking method, consolidated lists of responses, were developed by taking an average of ranks given by each participant to each response in the lists. In the list 'means of TII', (*Supplementary File 3*) the 'involvement of tobacco industry role players' across each 'theme of TII' was considered to be 'present' only when the final rank order of responses received consensus from at least half (at least five) of the participants during the step two of the power ranking method.

Ethics Considerations: The study was approved by the Institutional Ethics Committees of Jawaharlal Institute of Postgraduate Medical Education and Research (IEC ref no.- JIP/IEC/2017/0477 and Post Graduate Institute of Medical Education and Research, Chandigarh (IEC ref No. PGI/IEC/2017/565). The duly signed consent forms were taken from the respondents via email before conducting the interviews, with an option to withdraw from the study at any point of time. The study was conducted and reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ)[23].

Results

A total of 26 (14 by Institute 1 and 12 by Institute 2) in-depth interviews were conducted with past and current stakeholders at the various levels in the field of tobacco control. Majority of them were males (84.6%) and most were in

service (73.1%) i.e. they were serving either a government-institution (38.5%), a non-government institution (42.3%), or a private organization (19.2%). Half of them (57.7%) were engaged in tobacco control activities from the last 5-10 years. The characteristics of study participants are summarised in **Table-1**.

Table- 1: General details of the respondents invited for in-depth interviews.

	Institute 1	Institute 2	Total
Total	14 (100)	12 (100)	26 (100)
Gender			
Male	11 (78.6)	11 (91.7)	22 (84.6)
Female	3 (21.4)	1 (8.3)	4 (15.4)
Age			
25-45years	3 (21.4)	5 (41.7)	8 (30.8)
45-above	5 (35.7)	5 (41.7)	10 (38.5)
Not mentioned	6 (42.8)	2 (16.6)	8 (3.8)
Occupation status			
In service	8 (57.1)	11(91.7)	19 (73.1)
Retired	1 (7.1)	1(8.3)	2 (7.7)
Self employed	5 (35.7)	-	5 (19.2)
Organization			
Government	5 (35.7)	5 (41.7)	10 (38.5)
Non-Government	4 (28.5)	7(58.3)	11 (42.3)
Private	5 (35.7)	-	5 (19.2)
Years of Association with tobacco control			
5-10 years	10 (71.4)	5 (41.7)	15 (57.7)
11-20 years	2 (14.3)	5 (41.7)	7 (26.9)
20 years above	2 (14.3)	2 (16.6)	4 (15.4)

Almost all respondents perceived tobacco industry as 'Manufacturers' (Mean score = 9) while more than half of them associated 'advertisers', 'public relation (PR) companies', 'wholesalers', 'vendors', and 'Government firms having TI stocks' as tobacco industry. (**Table-2**). Power ranking method on prioritizing the players of tobacco industry's involvement in various themes of TI interferences showed that the 'manufacturers' and 'PR companies' were involved in all six types of industry interferences identified in the study. Industry led unions and farmer's corporations were involved in all types of interferences except Tobacco Advertising, Promotion, and Sponsorship (TAPS) activities. Industry sponsored hospitality sector was also involved in all types of interferences except hampering implementation of tobacco control in the country (**Table 3**). Majority of role players including 'wholesalers', 'bidi rollers', 'politicians', 'bureaucrats' and 'civil society organizations' were found to be associated with four types of industry led interferences in the country. (**Table 4**)

Table 2: Perception of study participants regarding Tobacco Industry using 'Power Ranking Methodology'.

Stakeholders	Average score (N=10)
Manufacturer	9
Wholesaler	6.8
Vendors	6.2
Advertisers	7
PR Company	6.7
Government with tobacco stocks	5.8
Government without tobacco stocks	2.2
Tobacco union workers	4.6
Farmers	3.8
Farmers corporations	4
Pension funds and other Financial incentive schemes	2.6
Banks and financial institutions	3.6
Bidi rollers	4.6
Politicians	5
Bureaucrats	4
Civil Society Organization	3.6
Hospitality Industry	0.6

Table 3: Role of tobacco industry in interfering tobacco control activities in India

Themes	Sub-themes
Influencing the policy and administrative decisions	Projected revenue generation and livelihood creation
	Providing sponsorships for government events & political parties
	Using policy loopholes
	Offering undue favors
	Lack of prioritization towards tobacco control
Interference with implementation of tobacco control laws and activities	Interference in the judiciary system
	Interfering with work of tobacco control officials
	Interference in functioning of NGOs who work on tobacco control
	Prompting sellers for non-cooperation with tobacco control officials
False propaganda and hiding the truth	Exaggerating the economic impact of tobacco and loss of livelihood
	Hiding facts about tobacco harms
	Promoting CSR activities to gain social respectability
	Hiding involvement in sponsored events
	Misguiding tobacco growers
Manipulating through front action groups	Instigating protests and non-cooperation
	Threatening tobacco shop owners
Rampant tobacco advertising and promotion activities	Promoting surrogate advertisements
	Creating new customer base with attractive offers
	Support and bonus for tobacco shops and vendors
Others	Evidence of Government honoring tobacco industry officials
	Poor awareness on harmful effects of tobacco among ancillary stakeholders of tobacco industry
	<u>Lack of cohesion at institutional levels</u> for tobacco control discussion at state and national level
	Lack of understanding and support for tobacco control initiatives
	Situational priority i.e. tobacco control taking backseat over other priority issues

Table 4: Perception of study participants regarding involvement of “Tobacco industry role players” in various identified themes.

Tobacco industry role players	Theme 1 (<i>Influencing the policy and administrative decision</i>)	Theme 2 (<i>Interference with implementation of tobacco control laws and activities</i>)	Theme 3 (<i>False propaganda and hiding the truth</i>)	Theme 4 (<i>Manipulating front action groups</i>)	Theme 5 (<i>Rampant TAPS activities</i>)	Theme 6 (<i>Others</i>)
Manufacturer	Y	Y	Y	Y	Y	Y
Wholesaler		Y	Y	Y	Y	
Vendors	Y	Y			Y	
Advertisers		Y	Y		Y	
PR Companies	Y	Y	Y	Y	Y	Y
Government with tobacco stocks	Y	Y		Y		Y
Government without tobacco stocks		Y		Y		Y
Tobacco union workers	Y	Y	Y	Y		Y
Farmers			Y	Y		Y
Farmers corporations	Y	Y	Y	Y		Y
Pension funds and other financial incentives schemes			Y	Y		
Banks etc.	Y	Y		Y		
Bidi rollers	Y	Y		Y		Y
Politicians	Y	Y		Y	Y	
Bureaucrats	Y	Y	Y	Y		
Civil Society Organizations	Y		Y	Y	Y	
Hospitality Industry	Y		Y	Y	Y	Y

"TI are various kinds of people who lead or who are part of tobacco production and selling (tobacco). Whosoever works for furthering the interests of TI are also part of TI; even though they may be peers, packagers, marketers, or advertisers are also TI." (One respondent).

"It's an established industry which is present in both organized and unorganized industry and well connected (politically)." (a health professional)

Interference of tobacco industry with tobacco control activities

The analysis of all the key informant interviews regarding interference of TI with tobacco control activities generated six themes and categories as shown in **Table 3** and Figure 1

1. Influencing the policy and administrative decisions

TI has been seen by participants as a prime intruder in policy making and key administrative decisions of the government. The participants opined that TI uses monetary and power tactics to influence policy makers in placing tobacco control to backseat.

Nearly everybody was of the opinion that TI structures significant supporters towards income for the administration and making business for some families like tobacco producers and tobacco venders. A participant surmised that TI has been traditionally involved in various governmental development projects which is a direct contradiction to Article 5.3 of FCTC.

"TI are spending crores of money in various states. They are sponsoring a lot of money in the food industry." (A tobacco control advocate)

"Recently we had got an order issued for increased taxation on tobacco products which was immediately reversed by our government, possibly due to pressure (of TI). Similarly, political leaders opposed the ban of Gutka (oral chewable tobacco) in parliament on the pretext of loss of income of farmers" (A tobacco control advocate)

The participants felt that TI creates an impression of 'no immediate threat associated with tobacco' among the public, which results in lack of public pressure on policy makers and politicians in framing effective tobacco control policies.

"Unlike accident and epidemics, tobacco use is not seen as an immediate danger to politicians and public, which is effectively utilized by TI. Whenever we go to public for a raid (COTPA enforcement), they throw a question on us, asking, 'why don't you close the tobacco companies rather than making the people suffer?'" (A government official)

The respondents also shared that many political parties and officials in the government receive favors from TI, which undermine the tobacco-related policy decisions.

"In one of our state's budgets, then minister declared a 5% VAT on bidis, which was immediately reversed to zero percent on the behest of TI, which we could sense." (A government official)

"The government's framework is unreactive towards tobacco control, the huge amount of cost involved with care of tobacco-related morbidities and mortalities. Lack of priority for tobacco control, poor funding, no dedicated staff exclusively for tobacco control and frequent transfer of trained staff explains that." (A tobacco control activist).

Tobacco is still not considered as an illegal product and no license is needed for processing, manufacturing or selling of tobacco products unlike liquor by the law of the land. TI makes use of this argument to convince policy makers in making tobacco products easily accessible at various Point of Sale.

"The biggest challenge for us is that we are one of the largest tobacco-growing and exporting countries. It's not an illegal product. TI use this argument for its easy accessibility in markets" (A health professional)

TI takes advantage of slow legal proceedings and poor implementation of tobacco control laws. The conflicting orders from different ministries provide opportunity for the TI to carry out promotional activities.

"TI have people who find loopholes in government policies, which leads to slowing of legal proceedings." (A government official)

The participants reported undue favors being offered by the TI representatives to higher officials in the form of gift hampers or financial support to the organizations as a tool to influence them to take policy decisions in their favour.

"TI also affects the opinion of the committee that constitutes to finalize the policy rules and regulations" (A study participant).

"One of the Corporation official's daughter marriage was completely conducted by the TI, starting from booking hall to buying jewelry and everything for the wedding was managed by the Gutka industry." (A tobacco control activist)

"Once the Gutka industry people came and offered undue favors. 'We will give you one crore and if you are finding it difficult to receive as a cash, then, we will buy you a house in the centre of the city". (A tobacco control activist)

Most of the respondents felt that the TI makes use of existing corruption within the system and week political setup to their benefit.

"TI tries to build pressure through their political representatives to delay or dilute the policies." (A participant).

"Vested interests of politicians results in lack of their will to combat Tobacco menace." (A participant)

Few of the respondents threw light on the way how TI manipulates policy making and implementation by challenging such procedures in court by using fake documents and poorly generated scientific evidence. Respondents reported witnessing instances where the TI had used fake of self-sponsored researches in favour of TI.

"Smokeless tobacco lobby always tries to threaten them. They also support high-level officials to refine the fake evidence which are provided by TI in support of their business." (A respondent)

"TI influences people, law enforcers, policy makers, doctors, lawyers, scientist, and high-level official against the good work done by you." (A respondent)

2. Interference with implementation of tobacco control laws and activities

The participants were of the opinion that since TI is a well-established sector with huge amount of money, they interfere with implementation of tobacco control laws and activities by influencing judiciary, implementing officials, non-government officials and merchant association or tobacco sellers. The respondents stated that legal challenges (litigations, RTIs etc.), offering undue favors , issuing threats are being used as weapons by the TI to interfere in implementation of tobacco control laws.

"TI has top level lawyers who challenge every favorable decision in the court of law, which dilutes effective implementation" (A tobacco control advocate).

"After a state high court had given an order about the 85% pictorial warning on tobacco packets, TI went to court several times which delayed its implementation." (An academician and researcher)

"TI representatives met me with an only agenda to stop supporting govt. initiatives in tobacco control program." (A public health activist)

"TI threatened me for implementing tobacco control activities in my state and even filed many RTIs to build the pressure." (A government official)

"Sometimes, when we are creating awareness among shopkeepers, some agents used to come from a particular company, and question us why are we stopping their business?" (A tobacco cessation expert)

"Unfortunately, one or two of the shopkeepers who received the award for not selling the product also started selling it (tobacco) again because of the threat (from tobacco dealers) and also the public is expecting us to sell it." (A

respondent

"A lot of money power (stressed). So, what can the police do when they are informed not to enforce." (A health professional)

"He came and opposed my public awareness program on the railway station. Why are you propagating this at all?" (An NGO official)

"Once, when we were traveling, a person (from TI) had accidentally or purposefully hit our vehicle and issued threat." (A leading tobacco control advocate)

"Foundation for Smoke Free World associated with a multinational tobacco company, is trying to influence people who are working for tobacco control. This foundation approached many tobacco control advocates through one to one meetings and mails also. The foundation approached President of an association but he denied their proposal. I sense that TI has used its financial muscle power to cancel FCRA of many associations." (A respondent)

"Not approached as an individual but two prominent national organizations are being approached by TI to support their school Intervention program." (Director of an organization)

Most of the respondents said that the TI creates a non-cooperative attitude among the distributors and point-of-sale owners by performing various activities like installing and replacing advertisement boards removed during enforcement drives, compensating for losses in case of seizures or challans.

"A point of sale owner told me that TI people came to them and reimburse challan (fine) money and even replace my advertisement boards removed in enforcement drives" (An academician and researcher)

"TI instructs the sellers of this product (cool lips- a flavored form of smokeless tobacco) to distribute among the children for which they pay us incentives." (A tobacco control enforcing official)

Most of the stakeholders opined that there is dearth of awareness at all levels i.e. among the stakeholders, the enforcers, the policy makers and the masses as a whole, which hinders proper implementation of the tobacco control laws.

"Law enforcers are not very much aware about the COTPA and other tobacco control laws." (A Director of a NGO)

"Lack of awareness and passion for tobacco control is the root cause of the challenges that came up during the implementation of tobacco control policies in the state." (A Deputy Director working in tobacco control)

3. False propaganda and hiding of truth

Responses from the interviews provided an insight into how the TI paints a bright picture in front of public and policy makers and hide their vested interests under the garb of health promotion social activities performed by them.

Many responses from the interviewees highlighted the fact that TI undertakes corporate social responsibility (CSR) by which they depict their companies as ethically correct and economically productive to the society.

"TI offered to support our school intervention program, which we denied" (A tobacco control expert)

"Earlier, we (in NGO) used to carry out only the tobacco control activities in collaboration with other NGOs. But, when the tobacco companies started CSR activities, they started funding many NGOs, which resulted in rifts between NGOs to garner funds from them (TI)." (A leading tobacco control advocate)

"TI want to build hospitals, and if the government is allowing that, then it will become the biggest threat." (Director of a NGO)

By discrediting scientific evidence, TI misguides the existing as well as future customers and also discourages tobacco users to quit.

"They (TI) are advocating that the tobacco is not harmful, tobacco is not causing cancer. They have many such studies (false evidence) to prove their statements". (An academician and researcher)

Misleading claims by TI representatives, of being a support for global tobacco regulation that aligns with the FCTC, was reported by few respondents

"A person who worked for tobacco control ,later joined as the head of 'Foundation for Smoke Free World', an initiative by a leading multinational tobacco company, wrote a mail to about 300 people all over the globe to join their organization and the people who did not know much about TI easily accept his proposal." (A Behavioral Scientist)

"People participate in such programs (conducted/sponsored by tobacco companies) without knowing that they are conducted by tobacco companies; like cultural shows, cultural events". (A public-health professional)

Tobacco growing is the only means of earning for a section of people. For their business interests, the TI doesn't want the tobacco growers to switch over to other means of livelihood.

"Most of them, either tobacco growers, or tobacco users are not aware of the big industry involved. Only middlemen are aware of the industry nexus." (A leading health professional)

"They are saying that, 'we are increasing the wage for them (bidi workers), which affirms belief of workers in them (TI).'" (A leading tobacco control activist)

4. Manipulating front action groups

Most of the respondents stressed upon the manipulative powers of the TI. As per them the main tactics used by the TI were threats and maneuvering acts.

Threats of legal action are a popular means used by the TI to intimidate governments and activists who introduce and support effective tobacco control policies. Others provide physical threats to them. As per the respondents the mere threat of such litigations and physical threats discourages the whole implementation process.

"There is large production house of a tobacco company in the State, so the industry always tries to delude our efforts. Smokeless tobacco lobby always tries to threaten our staff" (An Executive Director of an NGO)

"TI tries their best efforts to influence public health policies by providing them with policy loopholes and manipulating the facts. They are all directed towards the single motive of increasing their business." (A Manager working with an NGO)

"When we ask them (tobacco sellers), why they are again selling, they tell that because of the physical threat (from tobacco dealers)" (A tobacco cessation advocate)

With a vested interest, the tobacco company instigates the front action groups to protest the implementation of tobacco control laws citing livelihood issue and harassment.

"I'm more than closely working with the government tobacco control cell. See, recently they have instigated the retailers to protest, over the livelihood issue." (A leading health professional working for an NGO)

"TI picks the merchant association or restaurant association, push them to the front who then submit memorandums to the collector". (A leading tobacco control advocate)

5. Rampant TAPS activities

As per the respondents the TI uses tobacco advertising, promotion, and sponsorship (TAPS) to increase consumption of their products. The TI uses deceptive, misleading, and predatory tactics to make tobacco use appear glamorous and socially acceptable, while minimizing perceptions of products' adverse health effects.

A respondent working in the implementation sector said that the TI supports distributors and wholesalers by performing various activities like paying daily wages to petty sellers and providing signage's and other posters mandated under law to these retailer/vendors etc. Similarly, by endorsing other brands and partnering with other organization for sponsored events, they indirectly advertise their company. This persuades the existing customers from quitting tobacco use.

"They do things indirectly, and it is like hide and seek game with them (tobacco companies); because, surrogate advertisements are still there, which we (government) need to find or somebody has to inform us." (A public health professional)

"We have also taken efforts to stop various competitions like 'Sun-feast competition', 'Spell bee', and 'Mangal deep' singing competitions. So, these are against that order (Order 242)." (An advocate)

Besides, TI uses different tactics to create a new customer base and maintain the existing one. Lowering of price and selling components separately was another tactic.

"We got to know that the TI came up with two cigarette pack. So, that is a pack (tobacco pack) and it's not a loose cigarette." (An academician)

"We convinced the new government to ban Gutkha. But, since then, we see that Gutkha is being marketed with tobacco and betel leaves separately in smaller packets and reducing the rates." (An academician).

Flavored chewable tobacco products at point-of-sale attract new customers especially students and children.

"We had recently faced difficulty to seize a product named 'Cool tips'. This is a chewable form of tobacco sold like chocolates targeting the school children. The pictures of the product are also available on the internet." (A tobacco control enforcing official).

TI provides financial support in the form of reimbursement for the penalty imposed by officials and bonuses for selling tobacco products. This encourages the tobacco sellers and vendors to continue promoting tobacco products despite legal actions.

"Those cigarette companies, dealers used to promote the product by giving some bonus or cash prizes to the shopkeepers; they (shopkeepers) want that also." (A tobacco cessation advocate)

6. Others

Certain themes were generated that couldn't be categorized into any of the above-mentioned major domains were compiled to constitute the sixth domain.

1. *Government honoring TI officials (e.g.: a leading cigarette manufacturers CEO was awarded India's highest civilian award). Honoring TI officials acts as a catalyst for TI to expand their business.*
2. *Poor awareness on harmful effects of tobacco among ancillary stakeholders of TI (e.g. tobacco plant growers, tobacco sellers) The TI takes advantage of the lack of awareness on harmful effects of tobacco among lower level stakeholders.*
3. *Lack of common platform for tobacco control discussion (reason for ineffective, uncoordinated decision making and poor implementation of tobacco control laws)*
4. *Lack of understanding of tobacco control and limited support among government officials and policymakers (especially elected politicians) with respect to tobacco control. Situational priority for other communicable diseases, poor funding, and lack of understanding on tobacco control among government officials, poor coordination between different government departments prompt TI to flourish their business.*
5. *Situational priority (several immediate issues are prioritized over tobacco control at the grassroots)*

Challenges faced and the factors perceiving to the same

Many factors pose challenges at various level of tobacco control. Our respondents enumerated a list of challenges faced by them during the implementation of the tobacco-control activities. The challenges are at different levels and encroach the domain identified earlier in **table 3**. Different stakeholders, attempt interference in different domain as summarised in **table 4**. The TI deploys different strategies of interference to persuade the public and decision-makers. The detailed taxonomy for these strategies has been explicitly described in **Table 5**, with respect to the specific clause and recommendation of article 5.3 that is either violated or in a clear contradiction to Article 5.3 specifically.

Table 5: Tobacco industry interference and actors which challenge tobacco control efforts, based on responses of tobacco control experts who participated in the study.

Tactic	Goal	Key stakeholders for tobacco industry	Example	Violation or contradiction to the guiding principles of article 5.3
Intimidation	Use its power to harass and threaten tobacco control community	Politician and bureaucrats	Recent cancellation of permissions of tobacco control organisations	Clause 3, 9
Creating alliances and front groups	Present exaggerated and widespread negative impact tobacco control legislation/ tobacco control policies	Civil society, farmers networks etc.	FAIFA, State level farmers associations All India Bidi Federation	Clause 19 Recommendation 1.2
Supporting Government agencies that assist tobacco sector	Garner support from within the government	Ministries of Finance, Labour, Agriculture, Commerce, Tobacco Board	Various policy measures	Clause 3, 13,20,21 Recommendation 2.1, 3.1, 7.1
Political funding	Contribute to local and national political parties for campaign and seek favours from elected politicians	Political parties and party leaders	ITC annual reports Report of various tracts through which political funding is routed	Clause 22-23, 26-27 Recommendation 4.10, 4.11,6.4
Lobbying	Influence political and decision-making processes by presenting specious data and distracting officials from tobacco control	Front groups, PR firms	Lobbying by PR firms during Committee of Subordinate Legislation on pack warning (2015-16), TII	Clause 24-25 Recommendation 5.2
Litigation	Challenge laws and intimidate tobacco control advocates	Vendors, farmer associations, vested interest groups, Industry	Ghodawat pan masala pvt. ltd v/s the state of Maharashtra and others (WP no. 1632 OR 2012);	Recommendation 6.
Public relations	Shape public opinion by using media to and promote positions favourable to the tobacco industry and its allies	Media houses, PR companies, Government flagship programmes	Participation of tobacco companies in Government flagship programmes as a part of CSR	Clause 26-27 Recommendation 6.1,6.2
Philanthropy and Corporate Social Responsibility	Re-normalise and re-legitimize tobacco with society; gain social respectability by participating in social and economically relevant issues.	Through reputed NGOs and government schemes	Support neglected areas of investment. Eg: GPI supports vendors in flood affected areas by creating tobacco vends Partner with Govt in its flagship schemes like Swachh Bharat Abhiyan etc, floods/drought situation/ pandemic	Clause 26-27 Recommendation 6.2
Participate in decision making with government	Promise investments to state government	Industry associations and government bodies	Investments promised by ITC, GPI, and DS Group to states	Clause 28-29 Recommendation 7.1,7.2,7.3

A. Tobacco control not given highest priority by Government officials:

1. *Tobacco control is not high on the priority list of the government especially for departments other than health. Revenue earned from TI is projected and the loss due to tobacco-related diseases is undermined. Limited dedicated funds or workforce is allotted for tobacco control. Trained officials are frequently transferred which leads to intermittent implementation of tobacco control laws.*

2. *Inadequate political support against TI and limited documented evidence*

I. Lack of cohesion at institutional levels: *There is no common platform for discussion and adopting strategies for tobacco control. Many departments are not aware of their roles and responsibilities.*

II. Lack of funding from international donors and local corporates for tobacco control: *There are not many donors for tobacco control. The corporate world seems to restrain itself from investment in tobacco control.*

B. Difficulty in implementation and enforcement

i. *Lack of awareness: Second round of the Global Adult Tobacco Survey (GATS)-India (2016-17) [24] has depicted adequately high awareness regarding the harmful impact of tobacco use. However, some of the enforcing officials (police), politicians and judiciary system are still unaware of impact of tobacco use and its consequences on society. TI sponsored competitions, surrogate advertisements and partnerships are evidence for low awareness among various stakeholders*

ii. *Differential priority and lack of interest among enforcement officials: Most of the enforcing officials are multitasked. For instance, they are delegated with responsibilities of mitigating seasonal communicable diseases (like Dengue) which poses an immediate threat. Many senior officials are not convinced enough to attend all the tobacco-related meetings.*

Mode of approach by tobacco industry:

TI contacts different tobacco control activists and officials for preventing tempering with their business. Half of the participants reported to be approached by TI in various ways. Two of the participants were approached directly whereas three of them indirectly. One participant reported being approached by both means. Various reasons cited were 1) not to create awareness on harmful effects of tobacco 2) not to harass shopkeepers in the name of COTPA violations 3) enquire about tobacco cessation activities implemented by the government. Two participants reported being threatened directly by TI for interfering with their business. Even one participant was offered undue favors to distance from TI business. Three participants reported being aware of tobacco control advocates who were threatened by TI.

Discussion

Failure of government to adopt measures which are proven to reduce consumption of tobacco is mainly due to interference in policy-making process of government by the TI. This has been documented for the developed nations[25,26], but has not yet been attempted from the lower middle income countries including India, which are the major business hubs for TI. This is first of its kind study from India to document TII and its prevalent types. The findings can be used construct a model that is applicable on a larger scale for use by governments of various countries for recognising and preventing TII in policy-making decisions. Constructivist grounded theory was used to identify techniques and arguments which were later categorised into general strategies' and finally a taxonomy and TII activity model was created. We were able to identify six major domains under which TII activities can be classified through our qualitative analysis.

Most of the respondents agreed that TI is constantly influencing the policy and administrative decisions. WHO FCTC's Article 5.3 and guidelines for its execution took cognizance of this conflict and advocated steps to check influence of TI

on public health policy-making[9,27]. However, findings of contemporary report by FCTC signals requirement of further advancement to address this issue. [28]. Similar to our study, a report from three South-East Asian countries have demonstrated that the TI in Thailand tries to undermine the progress made in tobacco control, whereas in Indonesia, it has a free-hand to influence the government. Myanmar is encouraging foreign investments which include the TI; hence, it is open to the TI in spite of the tobacco-control endeavor taken by Ministry of Health and Sport[3]. Tobacco and tobacco-products generate large volumes of Indian Government's tax revenue, that can be as high as Rs. 43,000 crores annually[29]. Despite the fact that tobacco taxation is the most economical way to control tobacco use, it is the least utilized policy measure[30]. Such a large chunk of revenue puts them in a better position to be listened and take part in decision making processes. TI portrays themselves to be playing a major role in economic overhauling of their region from which they are operating through revenue generation and livelihood creation, and thus divert the attentions from other pertinent issues[31]. Another study from United States has also depicted that the economy of the six south-eastern states- also known as "*tobacco bloc*" of south-eastern United States- is extremely dependent on growing and manufacturing of tobacco. However, the jobs related to main tobacco sector in these states is merely 1.6% [32].

Similarly, sponsoring the events and organizations by corporates is well known tool for marketing, which corroborates the findings from the present study [28]. As per marketing literature, funding boosts image of a corporation, connects funding company's name with interests significant to a specific target group, provide fruitful exposure to product, target particular populations comprising groups which are hard to reach by conventional advertising modes, and bestows fame to company with help of highly seeable activities [33].

Our results depict that the TI takes benefit of the policy loopholes and tries to evade the obligations. Previous literature has also highlighted the fact that whenever a new law is made or the previous one is amended, there are always certain weak points left that are mostly due to professional lobbying by the TI, who then make use of those loopholes for their profit. This can be better explained by a case study from Malaysia, where the government, along with enactment of Control of Tobacco Product (Amendment) Regulations (CTPR) 2008, initiated pictorial health warnings (PHWs), and lack of a specification for minimum permitted pack size for PHWs was a major weakness in it, which resulted in importation of cigarette packs named '*Sampoerna Avolution*' in shape of small 'lipstick' boxes from Indonesia. There was serious manipulation in PHW on the packs and it was nearly unidentifiable[34].

On the same lines, most of the stakeholders observed interference with implementation of tobacco control laws and activities was observed as another common form of TI tactics. One of the vital tools for improving tobacco control is litigation, and judicial interpretations which have played a beneficial role by institutionalizing laws for tobacco control in many jurisdictions across the globe. However, it also remains one of the greatest challenges for the governments to protect tobacco control efforts from the litigation by the TI[35]. The TI interferes with the judiciary system and tobacco control activists to delay the process of decision making and implementation of the rules. Governments in various countries have been sued by the TI to check the laws completely or hamper their implementation. In Brazil, TI brought a judicial claim arguing that the National Health Surveillance Agency (ANVISA) didn't have legal authority for regulation of tobacco products, which resulted in delay of six years in implementation of ban on flavours and additives in tobacco products. Similarly in Bangladesh, due to the Bangladesh Cigarette Manufacturers' Association's (BMCA) interference, temporary permission to print pictorial health warnings (PHWs) on the lower parts of pack was granted to TI by law ministry on March 16, 2016 [36].

As the evidence for lethal impact of tobacco products started mounting, the companies created uncertainty and dispute regarding health risks, whilst at the same time had put filters on cigarettes and promised research into health effects of smoking to address growing public concern. Further, there are strong evidence from the Master Settlement Agreement in 1998 which shows that the radioactivity of tobacco smoke and its potential to cause cancer were known to TI, but they purposefully concealed this information [37]. In another instance in the USA, a network of consultants was developed

by TI to advocate ventilation as a “remedy” to second-hand smoke (SHS) [38]. An erroneous notion normalising smoking in a wide variety of contexts is contributed by sheer bulk of tobacco advertisement. [39–42] Under so-called corporate social responsibility (CSR) activities, millions of dollars are spent by TI each year, by giving scholarships to economically weaker students, funding projects for poverty alleviation, providing assistance during natural calamities, just to divert users’ concerns and keep a good image in front of them.

The industry has also constantly manipulated the front action groups. TI coherently works with several business allies and third parties to impede the implementation of effective tobacco control legislation and programmes. For instance, the International Tobacco Growers’ Association - a TI funded tobacco farmer’s lobby group - worked as front-group in developing countries. Tobacco manufacturers have repeatedly instigated the farmers to represent their views, however, but always had a blind-eye towards the long pending concerns of the farmers, who were not being benefitted from the profit that was being generated [26]. In an another instance, the TI documents state that a multinational tobacco company, contributed financially to existing hospitality associations, or it made its own “association” to halt the accretions in the development of smoke-free environments [43].

Laws are circumvented by TI to promote their products by using innovative and sometimes covert marketing strategies, in spite of existence of TAPS prohibition laws. When pressure on TI increased, indirect or proxy tobacco advertising such as dark advertising, brand stretching, corporate social responsibility (CSR) activities, promotion through films and new media such as internet, discounts or free-gift offers, distribution of free samples, sale of tobacco products in the form of children’s sweets/toys, etc. gained impetus. Guidelines for implementing Article 13 of FCTC, describe comprehensive TAPS ban to apply to all form of commercial communication, recommendation or action and all forms of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly.

There are certain strengths in our study. Firstly, it is the first study from India that attempts to document and categorise the TII in preventing the implementation of the effective anti-tobacco laws in the country. Secondly, it documented interviews from a wide range of players working in and around the TI in every sector and each part of the country to have a comprehensive picture of TI. However, there are certain limitations. Despite the fact that we interviewed variety of stakeholders, the sample size was small. Also, they were purposively selected from the existing knowledge of the investigation team. It is worth documenting here that the team of investigators were experts working at country and state level in tobacco control, and are quite knowledgeable about the sample panel for the study. Further, there were considerable similarities and compatibility in views of the stakeholders from varied branches and different part of within a country, indicating that they are indeed representative of the stakeholders.

There are several policy implications of this study. First, this work has highlighted various strategies that are traditionally being used by the TI for diluting and deterring specific policies, which can further provide insights to policy makers about their nefarious tactics. Second, the listed strategies will enable stakeholders to foresee and prevent the types of alliances the TI may attempt to build. Third, our work will stimulate academicians and researchers to go in-depth into various strategies highlighted in the paper for getting more evidence on this much important subject. Further, they can use the study to produce and communicate information to the policy makers, paying attention to audience and language. Fourth, the work underscores the need for ensuring clarity in official interactions with the TI and lobbyists. Ultimately, the strategies can provide public health advocates and policy-makers a dominating position by which they can plan narratives and strategies proactively and not merely react to those of TI. Further empirical work is required to document the country-based examples of TII and categorise them under each strategy domains presented in this study to further our stance in countering TII.

Conclusions

The present qualitative analysis documented a significant interference of TI in different domains with stakeholders acting at various hierarchical levels. This study can be a beneficial for the public-health community, and policy-makers at national, regional, and international levels to provide them insights about the nefarious tactics of TI, enable stakeholders to anticipate and pre-empt the kinds of alliances the TI may attempt to build, stimulate academicians and researchers to undertake in-depth analysis into various strategies highlighted in the paper and underscores the need for ensuring through transparency in official interactions with the TI and lobbyists. Future studies should focus on generating more evidence of TII on different domains emerged from the current paper like tobacco pack health warnings, TAPS, Electronic Nicotine Delivery Systems (ENDS) (e-cigarettes), and so on. If the public health experts or policy makers intend to face-off TI for legislative enforcement, they need to choose a scientific approach by generating enough evidence against TI that exposes its wicked face on global and regional fronts.

List Of Abbreviations

TI: Tobacco Industry

TII: Tobacco Industry Interference

WHO FCTC: World Health Organization Framework Convention on Tobacco Control

COREQ: Consolidated Criteria for Reporting Qualitative Research

TAPS: Tobacco Advertising, Promotion, and Sponsorship activities

COTPA: Cigarettes and Other Tobacco Products Act

GATS: *Global Adult Tobacco Survey*

CTPR: Control of Tobacco Product (Amendment) Regulations 2008

PHW: Pictorial health warnings

Declarations

Ethics approval and consent to participate: The study was approved by the Institutional Ethics Committees of Jawaharlal Institute of Postgraduate Medical Education and Research (IEC ref no.- JIP/IEC/2017/0477 and Post Graduate Institute of Medical Education and Research, Chandigarh (IEC ref No. PGI/IEC/2017/565). The duly signed consent forms were taken from the respondents via email before conducting the interviews, with an option to withdraw from the study at any point of time. The study was conducted and reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ).

Consent for publication: All author(s) read and approved the final manuscript.

Availability of data and materials: The transcripts of the in-depth Interviews analysed during the current study are available from the corresponding author on reasonable request, so as to protect the anonymity of the participants.

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Authors' contributions:

- **Sonu Goel and Sitanshu Sekhar Kar** were equally involved in the designing of the study, and manuscript writing, results analysis, review and approval of the final manuscript.
- **Madhur Verma was involved in** Manuscript Writing, Results Analysis Reviewed the final version of the paper, and submitted it for publication.
- **Parthibane Sivanantham, Bijay Nanda Naik** were involved in manuscript writing, results analysis, reviewed the final version of the paper.
- All authors have read and approved the manuscript

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Figures



Figure 1

Thematic diagram showing various tactics used by tobacco industry for survival

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